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April 28, 2000

Re: Trade Name: RespiEvents™

Common Name: RespiEvents™

Classification name: 21 CFR 870.1425 Class II Programmable Diagnostic Computer

NIMS, Inc. is submitting this Premark notification to FDA because an expanded indication for the intended use statement is requested for RespiEvents™ software. There have been no modifications or changes made to the predicate RespiEvents™ software and all information remains unchanged from the K942771 (approved 02/13/1996) submission.

This submission includes Appendix D which provides the performance testing information demonstrating that RespiEvents™ software can be used to provide analysis during activities of daily living, thereby supporting expanding the intended use statement as follows:

RespiEvents™ is a software package running on a personal computer that is intended to provide analysis of breathing patterns from RespiTrace technology, aid in identifying and classifying apneas, displaying heart rate changes from electrocardiographic waveforms, logging values from pulse oximetry, and displaying signals from physiologic recording devices such as a body position sensor and impedance pneumograph, in the wake and sleeping states *as well as activities of daily living*.

Section 12 and Appendix C of this submission provides a description and specifications of the software. This submission presents the comparative labeling information for the predicate device in Section 9. Information regarding the predicate device has been provided to the Agency in the RespiEvents™ submission K942771, approved 02/13/1996, and pertinent sections are referenced, summarized and reproduced in this submission for the convenience of the reviewer.

In addition to the comparative information, system testing and software validation has been conducted to demonstrate that the device performs according to its specifications and requirements. This information has been provided to the Agency in the RespiEvents™ submission K942771, approved 02/13/1996, and summarized in Appendix C of this submission. Software development information is also presented in Appendix C of this submission. The additional testing and results provided in Appendix D support the expanded indications for use, which is the purpose of this submission.

The activity study and data presented in Appendix supports the expanded indication of the Intended Use Statement of the RespiEvents™ software, viz., *as well as activities of daily living*. In this study, RespiEvents™ software has been shown to accurately detect a true breath during activity thus eliminating erroneous counting (as breaths) of artifacts occurring with torso movement during periods of activity. The user visually analyzes the RespiEvents™ waveform display and by adjusting the minimal acceptable

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volume (MAV) settings, the user is able to distinguish true breath waveforms from motion artifacts superimposed on waveforms. The ability of the RespiEvents™ software to distinguish and mark a true breath during periods of activity is the basis for stating that the software can be used during daily

activities of living. There were no additional safety and effectiveness concerns raised during the activity study. All safety and effectiveness data presented in the RespiEvents™ submission K942771 approved on 02/13/1996 remains unchanged.

It is the conclusion of NIMS, Inc., and Dr. Marvin Sackner that the information presented in this 510(k) submission supports the expanded use indication and because there are no modifications or changes to the RespiEvents™ software, the RespiEvents™ software used to collect additional data in support of this submission is equivalent to the predicate RespiEvents™ software. Questions concerning the information contained herein should be directed to Dr. Marvin A. Sackner, Chief Executive Officer at NIMS, Inc., at 305-534-3694, or by fax 305-534-9368.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2000

Marvin A. Sackner, M.D.
Chief Executive Officer at NIMS, Inc.
Non-Invasive Monitoring Systems, Inc
1840 West Avenue
Miami Beach, FL 33139

Re: K001369
RespiEvents™ software
Regulatory Class: II (two)
Product Code: 74 DQK
Dated: April 28, 2000
Received: May 1, 2000

Dear Dr. Sackner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

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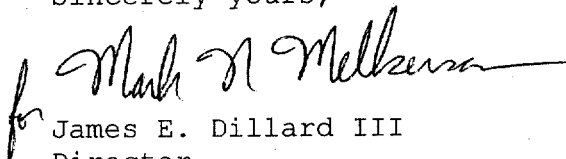
obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled,

"Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the typed name.

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Device
and Radiological Health

Enclosure

510(k) Number (if known): K001369

Device Name: RespiEvents, Version 4.2

Indications For Use:

RespiEvents™ is a software package running on a personal computer that is intended to provide analysis of breathing patterns from RespiTrace technology, aid in identifying and classifying apneas, displaying heart rate changes from electrocardiographic waveforms, logging values from pulse oximetry, and displaying signals from physiologic recording devices such as a body position sensor and impedance pneumograph, in the wake and sleeping states as well as activities of daily living.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Miller
Division of Cardiovascular & Respiratory Devices
510(k) Number K001369